

Message Text

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62

ORIGIN HEW-06

INFO OCT-01 ISO-00 ARA-10 OES-05 RSC-01 /023 R

66617

DRAFTED BY: DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

ARA/MEX:JKEANE INFO

----- 075122

R 062231Z JAN 75

FM SECSTATE WASHDC

TO AMEMBASSY MEXICO

UNCLAS STATE 002424

E.O. 11652: N/A

TAGS: ETRD, TBIO, MX

SUBJECT: RECALL OF DIAGNOSTIC CONTRAST MEDIA

1. FDA ADVISES THAT THE MALLINCKRODT, INC., 2ND AND MALLINCKRODT STREETS, ST. LOUIS, MISSOURI 63147 IS RECALLING ALL 50 ML. VIALS OF THE FOLLOWING PRODUCTS DUE TO THE POSSIBILITY OF NON-STERILITY:

1. CONRAY (MEGULMINE IOTHALAMATE INJECTION, U.S.P. 60 PERCENT) FO INTRAVENOUS UROGRAPHY AND ANGIOGRAPHY, LIST NO. 0953, NDC 19-0953-79 - ALL LOTS WITH THE FOLLOWING EXCEPTIONS:
BLR-E, BPX-B, BRX-A, BRX-B, BRX-D, BRX-E, BSL-A, BSL-B, BSL-C, BSL-E, BSR-B, BSR-C, BSR-D, BSR-X, BSR-G.

2. CONRAY 400 (SODIUM IOTHALAMATE INJECTION, U.S.P. 66.8 PERCENT) FOR INTRAVENOUS UROGRAPHY, INTRAVASCULAR ANGIO-CARDIOGRAPHY AND AORTOGRAPHY - LIST NO. 0954 NDC 0954-79 - ALL LOTS EXCEPT: BPY-D, BPY-E, BRT-B, BTG-B, BTG-C, BTG-D, B T G-E, BTG-G, BTL-A, BTL-B, BTL-D, BTL-E, BTL-G, BTN-C, B T N-D, BTN-E, BTN-G.

3. ANGIO CONRAY (SODIUM IOTHALAMATE INJECTION, U.S.P. 80 PERCENT) FOR INTRAVASCULAR ANGIO-CARDIOGRAPHY AND AORTOGRAPHY,
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LIST NO. 0926 NDC 19-0926-79 - ALL LOTS EXCEPT : BSG-A,

BSG-B, BSG-C, BSG-D, BSG-E, BSG-G.

4. VASCORAY (MEGULMINE IOTHALAMATE 52 PERCENT (W/V) AND SODIUM IOTHALMATE 26 PERCENT (W/V) (LIST NO. C337 NDC 19-C337-79 - ALL LOTS EXCEPT: BMA-G, BPP-A, BPP-B, BPP-C, BPP-D, BPP-G.

5. PYELOKON - R BRAND OF SODIUM ACETRIZOATE SOLUTION 20 PERCENT FOR RETROGRADE PYELOGRAPHY, LIST NO. 11488 NDC 19-1148-79 - ALL LOTS.

6. CYSTO-CONRAY (MEGULMINE IOTHALAMATE 43 PERCENT (W/V) FOR RETROGRADE CYSTOGRAPHY, CYSTO-URETHROGRAPHY, AND RETROGRADE PYELOGRAPHY, LIST NO. 7649 NDC 19-7649 - ALL LOTS.

2. FOREIGN CONSIGNEE, AS FOLLOWS:

REY-MOL, S.A., DE C.V. IXTAPALAPA D.F., MEXICO, APARTADO,
POSTAL 55426, MEXICO B, D.F., MEXICO

3. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE IF THE FIRM IS FAMILIAR WITH THE DETAILS OF THE RECALL. IN ADDITION, POST MAY WISH TO INFORM HOST GOVERNMENT DRUG CONTROL AUTHORITIES OF DETAILS OF THE RECALL. KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUG INDUSTRY, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 06 JAN 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE002424
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750005-0920
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750175/aaaacnvb.tel
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Original Classification: UNCLASSIFIED
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Reference: n/a
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Review Authority: buchant0
Review Comment: n/a
Review Content Flags:
Review Date: 24 FEB 2003
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Review Exemptions: n/a
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Review Markings:

Margaret P. Grafeld
Declassified/Released
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EO Systematic Review
05 JUL 2006

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Status: NATIVE
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TAGS: ETRD, TBIO, MX, US, MALLINCKRODT INC
To: MEXICO
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006